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REMARKS

Favorable reconsideration and allowance of the claims of the present application are respectfully requested.

In the Office Action dated January 10, 2007, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present application represents the multiple inventions. The Examiner asserts that a precise listing of inventive groups cannot be made due to the numerous variables in the claims, e.g. R, R_1, R_2, Ra-Rd, n, m, etc, and the Examiner provides the following twenty-four inventive groups as an example. The Examiner further asserts that the applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention.

Group I-IV	Claims 1-12 and 29 (in part), drawn to a method of treatment using compounds of formula (I) wherein: R_1, R_2, and Ra-Rd are as defined in Claim 1 excluding heterocyclyl and heterocyclylalkyl, classified in various subclasses in class 514; m+n is 0; R is aryl, pyrrolyl, indolyl, and thiophenyl, respectively.
Group V-VIII	Claims 1-12 and 29 (in part), drawn to a method of treatment using compounds of formula (I) wherein: R_1, R_2, and Ra-Rd are as defined in Claim 1 excluding heterocyclyl and heterocyclylalkyl, classified in various subclasses in class 514; m+n is 2; R is aryl, pyrrolyl, indolyl, and thiophenyl, respectively.
Group IX-XII	Claims 13-17, 20 and 23-28 (in part), drawn to a compound of formula (I) wherein: R_1, R_2, and Ra-Rd are as defined in Claim 1 excluding heterocyclyl and heterocyclylalkyl, classified in various subclasses in class 548; m+n is 0; R is aryl, pyrrolyl, indolyl, and thiophenyl, respectively.
Group XIII-XVI	Claims 13-17, 20 and 23-28 (in part), drawn to a compound of formula (I) wherein: R_1, R_2, and Ra-Rd are as defined in Claim 1 excluding heterocyclyl and heterocyclylalkyl,

	classified in various subclasses in class 546; m+n is 2; R is aryl, pyrrolyl, indolyl, and thiophenyl, respectively.
Group XVII-XX	Claims 18, 19 and 22 (in part), drawn to a process of preparing a compound of formula (I) wherein: R_1, R_2, and Ra-Rd are as defined in Claim 1 excluding heterocyclyl and heterocyclylalkyl, classified in various subclasses in class 514; m+n is 0; R is aryl, pyrrolyl, indolyl, and thiophenyl, respectively.
Group XXI-XXIV	Claims 18, 19 and 22 (in part), drawn to a process of preparing a compound of formula (I) wherein: R_1, R_2, and Ra-Rd are as defined in Claim 1 excluding heterocyclyl and heterocyclylalkyl, classified in various subclasses in class 514; m+n is20; R is aryl, pyrrolyl, indolyl, and thiophenyl, respectively.

Applicants elect, with traverse, the subject matter of Group IX wherein R_1, R_2 and Ra-Rd are as defined in Claim 13, m+n is 0, R is aryl excluding heterocyclyl and heterocyclylalkyl.

Applicants hereby reserve their right to file a divisional application(s) directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof for the following reasons.

Applicants respectfully request that the Restriction Requirement be withdrawn since it is not in compliance with 35 U.S.C. §121 and 37 C.F.R. §§1.141 and 1.142.

35 U.S.C. §121 provides that the Commissioner may restrict an application when two or more independent and distinct inventions are claimed in a single application (emphasis added). Similarly, 37 C.F.R. §1.141(a) permits restriction on condition that independent and distinct inventions are found within one application.

The United States Patent and Trademark Office has the burden of making a prima facie case that the subject matter is distinct and independent. The United States Patent and Trademark Office has not met this burden; the PTO has not shown that the various groups are distinct or independent. For example, Groups IX-XVI are drawn to products of a formula, Groups I-VIII are drawn to a method of using said products and Groups XVII-XXIV are drawn to a process of making said products.

Thus, the Office Action has not shown that the claimed subject matter in the various groups is independent and distinct as required.

Moreover, applicants submit that there is an interdependence between each of the groups alleged to be patentably distinct.

> MPEP §802.01 defines independent as follows:
> The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect...

Applicants respectfully submit that the present invention relates to pyrrolo-pyrazole and pyrazolo-azepine derivatives, to a process for their preparation, to pharmaceutical compositions comprising them and to their use as therapeutic agents, particularly in the treatment of diseases linked to disregulated protein kinases. Applicants further submit that the subject matter of Groups IX-XVI are drawn to products of a formula, Groups I-VIII are drawn to a method of using said products and Groups XVII-XXIV are drawn to a process of making products of said formula. Thus, Groups I-XXIV are interrelated and are not independent. Such Groups as defined by the Examiner, therefore, have a disclosed relationship.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants

have done herein, so as to encourage applicants to provide a more detailed disclosure of all aspects of their invention. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved. In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications that are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 228 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of

"obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, applicant respectfully urges the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of the defined twenty-four groups, one from the other, as presented by the Examiner.

In the Office Action, the Examiner further rejects the present claims under PCT Rule 13.1 and 13.2 as allegedly lacking unity of the invention. Specifically, the Examiner asserts that the compounds claimed do not define a contribution over the prior art WO 02/12242 A2.

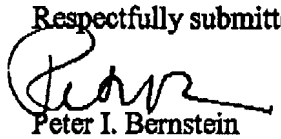
Applicants respectfully submit that as stated at 37 C.F.R. §1.475(b), a national stage application containing claims of different categories of invention are considered to have unity of invention if the claims are drawn only to ... (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said products, and that the claims of the present application meet this criterion.

Claims 13-17, 20 and 23-28 are directed to a product, pyrrolo-pyrazole and pyrazolo-azepine derivatives having the structural Formula (I). Claims 1-12 and 29 are directed to treating diseases caused by and/or associated with an altered protein kinase activity. These claims, in effect, are directed to the use of a product, the product being a compound, specifically a pyrrolo-pyrazole and pyrazolo-azepine, having the structural Formula I. Claims 18, 19 and 22 are directed to a process for preparing that pyrrolo-pyrazole and pyrazolo-azepine derivative product. Accordingly, consistent with the election and 37 C.F.R. §1.475(b), applicants respectfully request that, at least, the United States Patent and Trademark Office should consider the subject matter of these claims for examination herein.

Applicants further submit that WO 02/12242 discloses certain bicyclo-pyrazole derivatives and the use thereof in the treatment of diseases linked to disregulated protein kinases. However, the compounds of WO 02/12242 are markedly different from the compounds of the present invention. Specifically, formula (I) of WO 02/12242 bears a "NHR" group on position 3 of the pyrazole ring, while the substituent on position 3 of the pyrazole ring in the present compounds is not "NHR". Thus, the present application defines a contribution over the WO 02/12242 reference. Therefore, the unity rejection is overcome. Withdrawal of the rejection is respectfully requested.

In view of the foregoing comments, it is respectfully urged that the Examiner withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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